CLAIMS

What is Claimed is:

1. A method for obtaining a prognosis for a patient having or at risk of developing an inflammatory condition, the method comprising determining a genotype for one or more polymorphism sites in the plasminogen-activator-inhibitor-1 (PAI-1) gene for the patient, wherein said genotype is indicative of an ability of the patient to recover from an inflammatory condition, provided that the one or more polymorphism sites is not solely a polymorphism at a site corresponding to position 837 of SEQ ID NO.: 1.

2. The method of claim 1, wherein the one or more polymorphism sites includes position 12580 of SEQ ID NO.: 1 or a polymorphism site in total linkage disequilibrium thereto.

3. The method of claim 2, wherein the one or more polymorphism sites are selected from positions 5645, 7121, 7437, 8070, 8406, 9463, 9466, 12219, 12580, 13889 and 14440 in SEQ ID NO: 1.

4. The method of claim 1, wherein the genotype comprises a combination of two or more polymorphism sites, the combination being selected from the group of positions corresponding to SEQ ID NO:1 consisting of:

664 A and 2037 T;
664 A and 2362 -;
664 A and 2852 A;
664 A and 5834 A;
837 - and 2037 T;
837 - and 2362 -;
837 - and 2852 A;
837 - and 5834 A;

one of 5878 G and one of 7343 G, 13605 A and one of 7365 T, 7729 +, 7771 A, 12750 A and one of 4588 T, 5404 G, 5686 A, 5984 A

				11312 A; and
one of	2846 A and 10381 T and one of 6821 T and10381 T 9759 G and 10381 T	7365 T 7729 + 7771 A 12750 A	and one of	4588 T 5404 G 5686 A 5984 A 11312 A.

5. The method of any one of claims 1-4, further comprising comparing the genotype so determined with known genotypes, which are indicative of a prognosis for recovery from the same inflammatory condition as for the patient or another inflammatory condition.

6. The method of any one of claims 1-5, further comprising obtaining a plasminogen-activator-inhibitor-1 gene sequence of the patient.

7. The method any one of claims 1-5, wherein said determining of genotype is performed on a nucleic acid sample from the patient.

8. The method of claim 7, further comprising obtaining a nucleic acid sample from the patient.

9. The method any one of claims 1-8, wherein said determining of genotype comprises one or more of:

(a) restriction fragment length analysis;
(b) sequencing;
(c) hybridization;
(d) oligonucleotide ligation assay;
(e) ligation rolling circle amplification;
(f) 5′ nuclease assay;
(g) polymerase proofreading methods;
(h) allele specific PCR; and
(i) reading sequence data.

10. The method of any one of claims 1-9, wherein the genotype of the patient is indicative of a decreased likelihood of recovery from an inflammatory condition.

11. The method of claim 10, wherein the prognosis is indicative of severe cardiovascular or respiratory dysfunction in critically ill patients.

12. The method of claim 10 or 11, wherein the genotype is selected from the group of single polymorphism sites and combined polymorphism sites consisting of:

5645 T;
7121 G;
7437 T;
8070 A;
8406 C;
9463 G;
9466 T;
12219 C;
12580 G;
13889 C;
14440 A;
664 A and 2037 T;
664 A and 2362 -;
664 A and 2852 A;
664 A and 5834 A;
837 - and 2037 T;
837 - and 2362 -;
837 - and 2852 A; and
837 - and 5834 A.

13. The method of any one of claims 1-9, wherein the genotype of the patient is indicative of a increased likelihood of recovery from an inflammatory condition.

14. The method of claim 13, wherein the prognosis is indicative of less severe cardiovascular or respiratory dysfunction in critically ill patients.

15. The method of claim 13 or 14, wherein the genotype is selected from the group of single polymorphism sites and combined polymorphism sites consisting of:

5645 C;
7121 A;
7437 C;
8070 G;
8406 T;
9463 A;
9466 C;
12219 T;
12580 T;
13889 T;
14440 G;

one of	5878 G and one of	7365 T	and one of	4588 T
	7343 G	7729 +		5404 G
	13605 A	7771 A		5686 A
		12750 A		5984 A
				11312 A; and

one of	2846 A and 10381 T and one of	7365 T	and one of	4588 T
	6821 T	7729 +		5404 G
	9759 G	7771 A		5686 A
		12750 A		5984 A
				11312 A.

16. The method of any one of claims 1-15, wherein the inflammatory condition is selected from the group consisting of: sepsis, septicemia, pneumonia, septic shock, systemic inflammatory response syndrome (SIRS), Acute Respiratory Distress Syndrome (ARDS), acute lung injury, infection, pancreatitis, bacteremia, peritonitis, abdominal abscess, inflammation due to trauma, inflammation due to surgery, chronic inflammatory disease, ischemia, ischemia-reperfusion injury of an organ or tissue, tissue damage due to disease,

tissue damage due to chemotherapy or radiotherapy, and reactions to ingested, inhaled, infused, injected, or delivered substances, glomerulonephritis, bowel infection, opportunistic infections, and for patients undergoing major surgery or dialysis, patients who are immunocompromised, patients on immunosuppressive agents, patients with HIV/AIDS, patients with suspected endocarditis, patients with fever, patients with fever of unknown origin, patients with cystic fibrosis, patients with diabetes mellitus, patients with chronic renal failure, patients with bronchiectasis, patients with chronic obstructive lung disease, chronic bronchitis, emphysema, or asthma, patients with febrile neutropenia, patients with meningitis, patients with septic arthritis, patients with urinary tract infection, patients with necrotizing fasciitis, patients with other suspected Group A streptococcus infection, patients who have had a splenectomy, patients with recurrent or suspected enterococcus infection, other medical and surgical conditions associated with increased risk of infection, Gram positive sepsis, Gram negative sepsis, culture negative sepsis, fungal sepsis, meningococcemia, post-pump syndrome, cardiac stun syndrome, myocardial infarction, stroke, congestive heart failure, hepatitis, epiglotittis, E. coli 0157:H7, malaria, gas gangrene, toxic shock syndrome, mycobacterial tuberculosis, Pneumocystic carinii, pneumonia, Leishmaniasis, hemolytic uremic syndrome/thrombotic thrombocytopenic purpura, Dengue hemorrhaigic fever, pelvic inflammatory disease, Legionella, Lyme disease, Influenza A, Epstein-Barr virus, encephalitis, inflammatory diseases and autoimmunity including Rheumatoid arthritis, osteoarthritis, systemic lupus erythematosus, inflammatory bowel disease, idiopathic pulmonary fibrosis, sarcoidosis, hypersensitivity pneumonitis, systemic vasculitis, Wegener's granulomatosis, transplants including heart, liver, lung kidney bone marrow, graft-versus-host disease, transplant rejection, sickle cell anemia, nephrotic syndrome, toxicity of agents such as OKT3, cytokine therapy, and cirrhosis.

17. The method of any one of claims 1-16, wherein the inflammatory condition is systemic inflammatory response syndrome.

18. A method of identifying a polymorphism in a PAI-1 gene sequence that correlates with a patient prognosis, the method comprising:

a) obtaining PAI-1 gene sequence information from a group of patients;

b) identifying a site of at least one polymorphism in the PAI-1 gene;

c) determining genotypes at the site for individual patients in the group;

d) determining an ability of individual patients in the group to recover from the inflammatory condition; and

e) correlating genotypes determined at step (c) with patient abilities determined at step (d).

19. The method of claim 18, wherein the inflammatory condition is selected from the group consisting of: sepsis, septicemia, pneumonia, septic shock, systemic inflammatory response syndrome (SIRS), Acute Respiratory Distress Syndrome (ARDS), acute lung injury, infection, pancreatitis, bacteremia, peritonitis, abdominal abscess, inflammation due to trauma, inflammation due to surgery, chronic inflammatory disease, ischemia, ischemia-reperfusion injury of an organ or tissue, tissue damage due to disease, tissue damage due to chemotherapy or radiotherapy, and reactions to ingested, inhaled, infused, injected, or delivered substances, glomerulonephritis, bowel infection, opportunistic infections, and for patients undergoing major surgery or dialysis, patients who are immunocompromised, patients on immunosuppressive agents, patients with HIV/AIDS, patients with suspected endocarditis, patients with fever, patients with fever of unknown origin, patients with cystic fibrosis, patients with diabetes mellitus, patients with chronic renal failure, patients with bronchiectasis, patients with chronic obstructive lung disease, chronic bronchitis, emphysema, or asthma, patients with febrile neutropenia, patients with meningitis, patients with septic arthritis, patients with urinary tract infection, patients with necrotizing fasciitis, patients with other suspected Group A streptococcus infection, patients who have had a splenectomy, patients with recurrent or suspected enterococcus infection, other medical and surgical conditions associated with increased risk of infection, Gram positive sepsis, Gram negative sepsis, culture negative sepsis, fungal sepsis, meningococcemia, post-pump syndrome, cardiac stun syndrome, myocardial infarction, stroke, congestive heart failure, hepatitis, epiglotittis, E. coli 0157:H7, malaria, gas gangrene, toxic shock syndrome, mycobacterial tuberculosis, Pneumocystic carinii, pneumonia, Leishmaniasis, hemolytic uremic syndrome/thrombotic thrombocytopenic purpura, Dengue hemorrhaigic fever, pelvic inflammatory disease, Legionella, Lyme disease, Influenza A, Epstein-Barr virus, encephalitis, inflammatory diseases and autoimmunity including Rheumatoid arthritis, osteoarthritis, systemic lupus erythematosus, inflammatory bowel disease, idiopathic pulmonary fibrosis, sarcoidosis,

hypersensitivity pneumonitis, systemic vasculitis, Wegener's granulomatosis, transplants including heart, liver, lung kidney bone marrow, graft-versus-host disease, transplant rejection, sickle cell anemia, nephrotic syndrome, toxicity of agents such as OKT3, cytokine therapy, and cirrhosis.

20. A kit for determining a genotype at a defined nucleotide position within a polymorphism site in a PAI-1 gene sequence from a patient to provide a prognosis of the patient's ability to recover from an inflammatory condition, the kit comprising, in a package a restriction enzyme capable of distinguishing alternate nucleotides at the polymorphism site or a labeled oligonucleotide having sufficient complementary nucleotides to an adjacent sequence at or near the polymorphism site and capable of distinguishing said alternate nucleotides, provided that the polymorphism site is not solely a polymorphism at a site corresponding to position 837 of SEQ ID NO.: 1.

21. The kit of claim 20, where the polymorphism site corresponds to one or more of positions 5645, 7121, 7437, 8070, 8406, 9463, 9466, 12219, 12580, 13889 and 14440 of SEQ ID NO: 1.

22. The kit of claim 21, where the polymorphism site corresponds to position 12580.

23. The kit of claim 20, 21 or 22 comprising said restriction enzyme and an oligonucleotide or a set of oligonucleotides suitable to amplify a region surrounding the polymorphism site.

24. The kit of claim 23, further comprising a polymerization agent.

25. The kit of any one of claims 20-24, further comprising instructions for using the kit to determine genotype.

26. A method for selecting a group of patients for determining the efficacy of a candidate drug known or suspected of being useful for the treatment of an inflammatory condition, the method comprising determining a genotype for one or more polymorphism sites in the plasminogen-activator-inhibitor-1 gene for each patient, wherein said genotype is indicative of the patient's ability to recover from the inflammatory condition and sorting

patients based on their genotype, provided that the polymorphism site is not solely a polymorphism at a site corresponding to position 837 of SEQ ID NO.: 1.

27. The method of claim 26 further comprising, comparing patient response to the candidate drug based on genotype of the patient.

28. The method of claim 27, wherein patient response is determined by each patient's ability to recover from the inflammatory condition.